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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

HASMIK TER-MARTIROSYAN, et al.,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA & UPJOHN, INC.,
G.D. SEARLE LLC, and MCKESSON CORP.,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-4799-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia and Upjohn Company LLC¹ (improperly captioned in
3 Plaintiffs' Complaint as "Pharmacia & Upjohn, Inc.") ("Pharmacia & Upjohn"), and G.D.
4 Searle LLC ("Searle"), (collectively "Defendants") and file this Answer to Plaintiffs'
5 Complaint ("Complaint"), and would respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs and Decedent were
9 prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only
10 be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals
11 the specific time periods in which Plaintiffs and Decedent were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
15 Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny
16 that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
17 periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be
18 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
19 with their approval by the FDA. Defendants admit that, during certain periods of time,
20 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
21 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
22 providers who are by law authorized to prescribe drugs in accordance with their approval by the
23 FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25

26 ¹ Defendants deny that Pharmacia & Upjohn Company LLC ever designed, produced,
27 manufactured, marketed, sold, resold, or distributed Celebrex®, and deny that it is a proper party
28 in this suit. The foregoing statement regarding Pharmacia & Upjohn is incorporated by reference
in response to each and every paragraph of the Complaint referring to Pharmacia & Upjohn and/or
Defendants.

1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent
4 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Allegations Regarding Parties**

6 1. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
8 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 2. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
12 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
13 paragraph of the Complaint.

14 3. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
16 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
17 paragraph of the Complaint.

18 4. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and
20 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 5. Defendants admit that Pfizer is a Delaware corporation with its principal place of
23 business in New York. Defendants admit that, as the result of a merger in April 2003,
24 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph
25 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants
26 are without knowledge or information sufficient to form a belief as to the truth of such
27 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of
28 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, to

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1 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
2 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
3 paragraph of the Complaint.

4 6. Defendants admit that Searle is a Delaware limited liability company with its principal
5 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
6 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
7 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
8 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
9 Celebrex® in the United States to be prescribed by healthcare providers who are by law
10 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
11 the remaining allegations in this paragraph of the Complaint.

12 7. Pharmacia Corporation is not named as a Defendant in Plaintiff's Complaint.
13 Nevertheless, Defendants admit that Pharmacia is a Delaware corporation with its principal
14 place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and
15 that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of
16 Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-
17 promoted Celebrex® in the United States, including California, to be prescribed by healthcare
18 providers who are by law authorized to prescribe drugs in accordance with their approval by the
19 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 8. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
21 Celebrex® in the United States to be prescribed by healthcare providers who are by law
22 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
23 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
24 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
25 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
26 accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle
27 in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became
28 subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the

1 Complaint.

2 9. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
3 Celebrex® in the United States to be prescribed by healthcare providers who are by law
4 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
5 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
6 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
7 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
8 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
9 and effective when used in accordance with its FDA-approved prescribing information.
10 Defendants state that the potential effects of Celebrex® were and are adequately described in its
11 FDA-approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
13 remaining allegations in this paragraph of the Complaint.

14 10. Defendants state that the allegations in this paragraph of the Complaint regarding
15 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
16 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
17 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

18 **Response to Allegations Regarding Jurisdiction and Venue**

19 11. Defendants are without knowledge or information to form a belief as to the truth of the
20 allegations in this paragraph of the Complaint regarding Plaintiffs’ citizenship and the amount
21 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim
22 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of
23 interests and costs.

24 12. Defendants are without knowledge or information to form a belief as to the truth of the
25 allegations in this paragraph of the Complaint regarding the judicial district in which the
26 asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex®
27 was and is safe and effective when used in accordance with its FDA-approved prescribing
28 information. Defendants deny committing a tort in the State of California and deny the

1 remaining allegations in this paragraph of the Complaint.

2 13. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
 3 Celebrex® in the United States, including California, to be prescribed by healthcare providers
 4 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
 5 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
 6 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
 7 Celebrex® in the United States to be prescribed by healthcare providers who are by law
 8 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
 9 that Pfizer, Pharmacia, and Searle are registered to and do business in the State of California.
 10 Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors
 11 in interest” are vague and ambiguous. Defendants are without knowledge or information
 12 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.
 13 Defendants deny committing a tort in the State of California and deny the remaining allegations
 14 in this paragraph of the Complaint.

15 **Response to Allegations Regarding Interdistrict Assignment**

16 14. Defendants state that this paragraph of the Complaint contains legal contentions to
 17 which no response is required. To the extent that a response is deemed required, Defendants
 18 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
 19 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
 20 Panel on Multidistrict Litigation on September 6, 2005.

21 **Response to Factual Allegations**

22 15. Defendants are without knowledge or information sufficient to form a belief as to the
 23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
 24 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
 25 paragraph of the Complaint.

26 16. Defendants are without knowledge or information sufficient to form a belief as to the
 27 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical
 28 condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state

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1 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
2 prescribing information. Defendants state that the potential effects of Celebrex® were and are
3 adequately described in its FDA-approved prescribing information, which was at all times
4 adequate and comported with applicable standards of care and law. Defendants deny that
5 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
6 paragraph of the Complaint.

7 17. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury
14 or damage and deny the remaining allegations in this paragraph of the Complaint.

15 18. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
22 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
23 paragraph of the Complaint.

24 19. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
27 Celebrex® was expected to reach users and consumers without substantial change from the
28 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

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20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury

1 or damage and deny the remaining allegations in this paragraph of the Complaint.

2 24. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
9 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
10 paragraph of the Complaint.

11 25. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
14 Celebrex® was expected to reach users and consumers without substantial change from the
15 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 26. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
23 remaining allegations in this paragraph of the Complaint.

24 27. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
26 marital status and whether Decedent used Celebrex®, and, therefore, deny the same.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 28. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding Decedent's medical
2 condition or whether Decedent used Celebrex®, and, therefore, deny the same. Defendants
3 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
4 approved prescribing information. Defendants state that the potential effects of Celebrex®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendants deny
7 that Celebrex® caused Plaintiff or Decedent injury or damage and deny the remaining
8 allegations in this paragraph of the Complaint.

9 29. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
11 marital status and whether Decedent used Celebrex®, and, therefore, deny the same.
12 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
13 FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny that Celebrex® caused Plaintiff or Decedent injury or damage and deny the
17 remaining allegations in this paragraph of the Complaint.

18 30. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
20 marital status and whether Decedent used Celebrex®, and, therefore, deny the same.
21 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
22 FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent
26 injury or damage and deny the remaining allegations in this paragraph of the Complaint.

27 31. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's

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1 marital status and whether Decedent used Celebrex®, and, therefore, deny the same.
2 Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
3 consumers without substantial change from the time of sale. Defendants deny the remaining
4 allegations in this paragraph of the Complaint.

5 32. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
7 marital status and whether Decedent used Celebrex®, and, therefore, deny the same.
8 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 33. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
17 paragraph of the Complaint.

18 34. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
20 condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state
21 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
22 prescribing information. Defendants state that the potential effects of Celebrex® were and are
23 adequately described in its FDA-approved prescribing information, which was at all times
24 adequate and comported with applicable standards of care and law. Defendants deny that
25 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
26 paragraph of the Complaint.

27 35. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury
6 or damage and deny the remaining allegations in this paragraph of the Complaint.

7 36. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
14 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
15 paragraph of the Complaint.

16 37. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
19 Celebrex® was expected to reach users and consumers without substantial change from the
20 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 38. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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39. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

41. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

42. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

43. Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or

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1 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining
2 allegations in this paragraph of the Complaint.

3 44. Defendants state that the allegations in this paragraph of the Complaint regarding
4 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
5 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
6 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
7 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
8 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
9 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants
10 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
11 approved prescribing information. Defendants state that the potential effects of Celebrex®
12 were and are adequately described in its FDA-approved prescribing information, which was at
13 all times adequate and comported with applicable standards of care and law. Defendants deny
14 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

15 45. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
16 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
17 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
18 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
19 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
20 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
21 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
22 the remaining allegations in this paragraph of the Complaint.

23 46. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
24 that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United
25 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
26 accordance with their approval by the FDA. Defendants admit that, during certain periods of
27 time, Celebrex® was manufactured and packaged for Searle, which developed, tested,
28 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by

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1 healthcare providers who are by law authorized to prescribe drugs in accordance with their
2 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
3 in accordance with its FDA-approved prescribing information. Defendants state that the
4 potential effects of Celebrex® were and are adequately described in its FDA-approved
5 prescribing information, which was at all times adequate and comported with applicable
6 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
7 allegations in this paragraph of the Complaint.

8 47. Defendants state that the referenced article speaks for itself and respectfully refer the
9 Court to the article for its actual language and text. Any attempt to characterize the article is
10 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
12 this paragraph of the Complaint.

13 48. Defendants state that the referenced article speaks for itself and respectfully refer the
14 Court to the article for its actual language and text. Any attempt to characterize the article is
15 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
17 this paragraph of the Complaint.

18 49. Defendants state that the referenced FDA Update speaks for itself and respectfully refer
19 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
20 FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when
21 used in accordance with its FDA-approved prescribing information. Defendants state that the
22 potential effects of Celebrex® were and are adequately described in its FDA-approved
23 prescribing information, which was at all times adequate and comported with applicable
24 standards of care and law. Defendants deny the remaining allegations in this paragraph of the
25 Complaint.

26 50. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 51. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 52. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
11 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
12 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
13 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
14 and respectfully refer the Court to the study for its actual language and text. Any attempt to
15 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
16 the Complaint.

17 53. Defendants state that the referenced article speaks for itself and respectfully refer the
18 Court to the article for its actual language and text. Any attempt to characterize the article is
19 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 54. Defendants state that the referenced study speaks for itself and respectfully refer the
21 Court to the study for its actual language and text. Any attempt to characterize the study is
22 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
23 paragraph of the Complaint.

24 55. Defendants state that the FDA Medical Officer Review and FDA CLASS Review speak
25 for themselves and respectfully refer the Court to the Medical Officer Review and Class
26 Review for their actual language and text. Any attempt to characterize the Medical Officer
27 Review or Class Review is denied. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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1 56. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
2 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
3 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any
4 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

5 57. Defendants state that the referenced articles speak for themselves and respectfully refer
6 the Court to the articles for their actual language and text. Any attempt to characterize the
7 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
8 refer the Court to the study for its actual language and text. Any attempt to characterize the
9 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 58. Defendants state that the referenced article speaks for itself and respectfully refer the
11 Court to the article for its actual language and text. Any attempt to characterize the article is
12 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
13 paragraph of the Complaint.

14 59. Defendants state that the referenced articles speak for themselves and respectfully refer
15 the Court to the articles for their actual language and text. Any attempt to characterize the
16 articles is denied. Defendants deny the remaining allegations in this paragraph of the
17 Complaint.

18 60. Defendants state that the referenced article speaks for itself and respectfully refer the
19 Court to the article for its actual language and text. Any attempt to characterize the article is
20 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
21 Court to the study for its actual language and text. Any attempt to characterize the study is
22 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 61. Defendants state that the referenced Medical Officer Review speaks for itself and
24 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
25 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
26 allegations in this paragraph of the Complaint.

27 62. Plaintiffs fail to provide the proper context for the allegations concerning "Public
28 Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or

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1 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 63. Defendants state that the referenced article speaks for itself and respectfully refer the
4 Court to the article for its actual language and text. Any attempt to characterize the article is
5 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
6 paragraph of the Complaint.

7 64. Defendants state that the referenced study speaks for itself and respectfully refer the
8 Court to the study for its actual language and text. Any attempt to characterize the study is
9 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public
10 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
11 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

12 Defendants deny the remaining allegations in this paragraph of the Complaint.

13 65. Defendants admit that there was a clinical trial called APC. Defendants state that the
14 referenced article speaks for itself and respectfully refer the Court to the article for its actual
15 language and text. Any attempt to characterize the article is denied. Defendants deny the
16 remaining allegations in this paragraph of the Complaint.

17 66. Defendants state that the referenced article speaks for itself and respectfully refer the
18 Court to the article for its actual language and text. Any attempt to characterize the article is
19 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Data Safety
20 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
21 information or knowledge to form a belief as to the truth of such allegations and, therefore,
22 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 67. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 68. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
27 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
28 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 69. Defendants state that the referenced Medical Officer Review speaks for itself and
3 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
4 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
5 allegations in this paragraph of the Complaint.

6 70. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide
7 the proper context for the allegations concerning “other Celebrex trials” contained in this
8 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
9 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
10 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
11 that the referenced study speaks for itself and respectfully refer the Court to the study for its
12 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
13 remaining allegations in this paragraph of the Complaint.

14 71. Defendants state that the referenced article speaks for itself and respectfully refer the
15 Court to the article for its actual language and text. Any attempt to characterize the article is
16 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 72. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
18 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
19 therefore lack sufficient information or knowledge to form a belief as to the truth of such
20 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
21 themselves and respectfully refer the Court to the studies for their actual language and text.
22 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
23 this paragraph of the Complaint.

24 73. Defendants state that the referenced Medical Officer Review speaks for itself and
25 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
26 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
27 allegations in this paragraph of the Complaint.

28 74. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint

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1 are not directed toward Defendants, and therefore no response is required. To the extent that a
2 response is deemed required, Plaintiffs fail to provide the proper context for the allegations in
3 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.
4 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
5 such allegations and, therefore, deny the same. Defendants state that the referenced study
6 speaks for itself and respectfully refer the Court to the study for its actual language and text.
7 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in
8 this paragraph of the Complaint.

9 75. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
10 Complaint are not directed toward Defendants, and therefore no response is required. To the
11 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the
12 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
13 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
14 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
15 referenced study speaks for itself and respectfully refer the Court to the study for its actual
16 language and text. Any attempt to characterize the study is denied. Defendants deny the
17 remaining allegations in this paragraph of the Complaint.

18 76. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
19 Complaint are not directed toward Defendants, and therefore no response is required. To the
20 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the
21 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
22 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
23 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
24 referenced study speaks for itself and respectfully refer the Court to the study for its actual
25 language and text. Any attempt to characterize the study is denied. Defendants state that the
26 referenced article speaks for itself and respectfully refer the Court to the article for its actual
27 language and text. Any attempt to characterize the article is denied. Defendants deny the
28 remaining allegations in this paragraph of the Complaint.

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1 77. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants deny the allegations in this
3 paragraph of the Complaint.

4 78. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 79. Defendants state that allegations in this paragraph of the Complaint are not directed
8 toward Defendants, and therefore no response is required. To the extent that a response is
9 deemed required, Defendants state that the referenced article speaks for itself and respectfully
10 refer the Court to the article for its actual language and text. Any attempt to characterize the
11 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 80. Defendants deny the allegations in this paragraph of the Complaint.

13 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
18 remaining allegations contained in this paragraph of the Complaint.

19 82. Defendants deny any wrongful conduct and deny the allegations contained in this
20 paragraph of the Complaint.

21 83. Defendants deny any wrongful conduct and deny the allegations contained in this
22 paragraph of the Complaint.

23 84. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
28 paragraph of the Complaint.

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85. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and text. Any attempt to characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

87. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

88. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

89. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

90. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
6 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
7 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
8 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
9 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
10 paragraph of the Complaint.

11 91. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
16 Celebrex® in the United States to be prescribed by healthcare providers who are by law
17 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
18 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
19 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
20 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
21 accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription
22 medication which is approved by the FDA for the following indications: (1) for relief of the
23 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
24 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
25 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
26 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
27 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
28 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 92. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which at all times was adequate and comported with applicable standards of care and law.
7 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
8 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
9 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
10 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

11 93. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
16 Celebrex® in the United States to be prescribed by healthcare providers who are by law
17 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
18 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
19 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
20 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
21 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
22 paragraph of the Complaint.

23 94. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which at all times was adequate and comported with applicable standards of care and law.
27 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
28 Celebrex® in the United States to be prescribed by healthcare providers who are by law

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1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
2 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
3 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
4 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 95. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 96. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 97. Defendants deny the allegations in this paragraph of the Complaint.

20 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 99. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 100. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
6 Decedent used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful
7 conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the
8 remaining allegations in this paragraph of the Complaint.

9 101. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
14 remaining allegations in this paragraph of the Complaint.

15 102. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® are and were adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 103. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® are and were adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
26 the study for its actual language and text. Any attempt to characterize the study is denied.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

1 104. Defendants deny any wrongful conduct and deny the remaining allegations in this
2 paragraph of the Complaint.

3 105. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
5 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
6 and is safe and effective when used in accordance with its FDA-approved prescribing
7 information. Defendants state that the potential effects of Celebrex® are and were adequately
8 described in its FDA-approved prescribing information, which was at all times adequate and
9 comported with applicable standards of care and law. Defendants deny any wrongful conduct
10 and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to First Cause of Action: Negligence**

12 106. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
13 Complaint as if fully set forth herein.

14 107. Defendants state that this paragraph of the Complaint contains legal contentions to
15 which no response is required. To the extent that a response is deemed required, Defendants
16 admit that they had duties as are imposed by law but deny having breached such duties.
17 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
18 FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 108. Defendants state that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendants
25 admit that they had duties as are imposed by law but deny having breached such duties.
26 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 109. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
6 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
7 and is safe and effective when used in accordance with its FDA-approved prescribing
8 information. Defendants state that the potential effects of Celebrex® were and are adequately
9 described in its FDA-approved prescribing information, which was at all times adequate and
10 comported with applicable standards of care and law. Defendants deny any wrongful conduct
11 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

12 110. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
14 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
15 and is safe and effective when used in accordance with its FDA-approved prescribing
16 information. Defendants state that the potential effects of Celebrex® were and are adequately
17 described in its FDA-approved prescribing information, which was at all times adequate and
18 comported with applicable standards of care and law. Defendants deny any wrongful conduct,
19 deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this
20 paragraph of the Complaint.

21 111. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 112. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and

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Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' medical conditions and whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

114. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

115. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

116. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

117. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-

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1 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
2 providers who are by law authorized to prescribe drugs in accordance with their approval by the
3 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
4 consumers without substantial change from the time of sale. Defendants deny the remaining
5 allegations in this paragraph of the Complaint.

6 118. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 119. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
16 remaining allegations in this paragraph of the Complaint.

17 120. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
22 remaining allegations in this paragraph of the Complaint, including all subparts.

23 121. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
25 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
26 and is safe and effective when used in accordance with its FDA-approved prescribing
27 information. Defendants state that the potential effects of Celebrex® were and are adequately
28 described in its FDA-approved prescribing information, which was at all times adequate and

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1 comported with applicable standards of care and law. Defendants deny any wrongful conduct,
2 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 122. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
9 remaining allegations in this paragraph of the Complaint.

10 123. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
12 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
13 and is safe and effective when used in accordance with its FDA-approved prescribing
14 information. Defendants state that the potential effects of Celebrex® were and are adequately
15 described in its FDA-approved prescribing information, which was at all times adequate and
16 comported with applicable standards of care and law. Defendants deny any wrongful conduct,
17 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 124. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 125. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
27 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
28 and is safe and effective when used in accordance with its FDA-approved prescribing

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1 information. Defendants state that the potential effects of Celebrex® were and are adequately
2 described in its FDA-approved prescribing information, which was at all times adequate and
3 comported with applicable standards of care and law. Defendants deny any wrongful conduct,
4 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining
5 allegations in this paragraph of the Complaint.

6 126. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 127. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
14 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
15 and is safe and effective when used in accordance with its FDA-approved prescribing
16 information. Defendants state that the potential effects of Celebrex® were and are adequately
17 described in its FDA-approved prescribing information, which was at all times adequate and
18 comported with applicable standards of care and law. Defendants deny any wrongful conduct
19 and deny the remaining allegations in this paragraph of the Complaint.

20 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
21 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
22 Complaint.

23 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
24 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
25 Complaint.

26 130. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
27 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
28 Complaint.

Response to Third Cause of Action: Breach of Express Warranty

131. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

133. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

134. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

135. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 136. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 137. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
12 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that the potential
13 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
14 information, which was at all times adequate and comported with applicable standards of care
15 and law. Defendants admit that they provided FDA-approved prescribing information
16 regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the
17 Complaint.

18 138. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
19 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
20 Complaint.

21 139. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
22 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
23 Complaint.

24 140. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
25 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
26 Complaint.

27 **Response to Fourth Cause of Action: Breach of Implied Warranty**

28 141. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'

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1 Complaint as if fully set forth herein.

2 142. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
3 Celebrex® in the United States to be prescribed by healthcare providers who are by law
4 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
5 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
6 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
7 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
8 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 143. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants admit that they provided FDA-approved prescribing information regarding
15 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 144. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 145. Defendants state that this paragraph of the Complaint contains legal contentions to
22 which no response is required. To the extent that a response is deemed required, Defendants
23 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
24 approved prescribing information. Defendants state that the potential effects of Celebrex®
25 were and are adequately described in its FDA-approved prescribing information, which was at
26 all times adequate and comported with applicable standards of care and law. Defendants deny
27 any wrongful conduct, and deny the remaining allegations in this paragraph of the Complaint.

28 146. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
2 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a
3 prescription medication which is approved by the FDA for the following indications: (1) for
4 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
5 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
6 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
7 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
8 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
9 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
10 and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 147. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
13 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
14 and is safe and effective when used in accordance with its FDA-approved prescribing
15 information. Defendants state that the potential effects of Celebrex® were and are adequately
16 described in its FDA-approved prescribing information, which was at all times adequate and
17 comported with applicable standards of care and law. Defendants admit that they provided
18 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining
19 allegations in this paragraph of the Complaint.

20 148. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
22 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary
23 case, Celebrex® was expected to reach users and consumers without substantial change from
24 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 149. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
27 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
28 and is safe and effective when used in accordance with its FDA-approved prescribing

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information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

152. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

153. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

154. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

155. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint, including all subparts.

4 156. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 157. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
12 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
13 and is safe and effective when used in accordance with its FDA-approved prescribing
14 information. Defendants state that the potential effects of Celebrex® were and are adequately
15 described in its FDA-approved prescribing information, which was at all times adequate and
16 comported with applicable standards of care and law. Defendants deny any wrongful conduct,
17 deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining
18 allegations in this paragraph of the Complaint.

19 158. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 159. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
27 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
28 and is safe and effective when used in accordance with its FDA-approved prescribing

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1 information. Defendants state that the potential effects of Celebrex® were and are adequately
2 described in its FDA-approved prescribing information, which was at all times adequate and
3 comported with applicable standards of care and law. Defendants deny any wrongful conduct
4 and deny the remaining allegations in this paragraph of the Complaint.

5 160. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
7 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
8 and is safe and effective when used in accordance with its FDA-approved prescribing
9 information. Defendants state that the potential effects of Celebrex® were and are adequately
10 described in its FDA-approved prescribing information, which was at all times adequate and
11 comported with applicable standards of care and law. Defendants deny any wrongful conduct
12 and deny the remaining allegations in this paragraph of the Complaint.

13 161. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
15 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
16 and is safe and effective when used in accordance with its FDA-approved prescribing
17 information. Defendants state that the potential effects of Celebrex® were and are adequately
18 described in its FDA-approved prescribing information, which was at all times adequate and
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct
20 and deny the remaining allegations in this paragraph of the Complaint.

21 162. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
23 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
24 and is safe and effective when used in accordance with its FDA-approved prescribing
25 information. Defendants state that the potential effects of Celebrex® were and are adequately
26 described in its FDA-approved prescribing information, which was at all times adequate and
27 comported with applicable standards of care and law. Defendants deny any wrongful conduct
28 and deny the remaining allegations in this paragraph of the Complaint.

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163. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

164. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

166. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

167. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

168. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

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169. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

170. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

171. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

172. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

173. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing

1 information. Defendants state that the potential effects of Celebrex® were and are adequately
2 described in its FDA-approved prescribing information, which was at all times adequate and
3 comported with applicable standards of care and law. Defendants deny any wrongful conduct
4 and deny the remaining allegations in this paragraph of the Complaint.

5 174. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
6 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
7 Complaint.

8 **Response to Seventh Cause of Action: Negligent Misrepresentation**

9 175. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
10 Complaint as if fully set forth herein.

11 176. Defendants state that this paragraph of the Complaint contains legal contentions to
12 which no response is required. To the extent that a response is deemed required, Defendants
13 admit that they had duties as are imposed by law but deny having breached such duties.
14 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
15 Celebrex® in the United States to be prescribed by healthcare providers who are by law
16 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
17 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
18 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
19 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
20 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 177. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 178. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 179. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint, including all subparts.

12 180. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
14 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was
15 and is safe and effective when used in accordance with its FDA-approved prescribing
16 information. Defendants state that the potential effects of Celebrex® were and are adequately
17 described in its FDA-approved prescribing information, which was at all times adequate and
18 comported with applicable standards of care and law. Defendants deny any wrongful conduct
19 and deny the remaining allegations in this paragraph of the Complaint.

20 181. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 182. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
27 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
28 Complaint.

1 183. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
3 Complaint.

4 184. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or
5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
6 Complaint.

7 **Response to Eighth Cause of Action: Wrongful Death**

8 185. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
9 Complaint as if fully set forth herein.

10 186. Defendants state that this paragraph of the Complaint contains legal contentions to
11 which no response is required. To the extent that a response is deemed required, Defendants
12 are without knowledge or information sufficient to form a belief as to the truth of the
13 allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's marital
14 status, and, therefore, deny the same. Defendants are without knowledge or information
15 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint
16 regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants deny
17 any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and
18 deny the remaining allegations in this paragraph of the Complaint.

19 187. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 188. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint, including all subparts.

3 189. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
5 marital status, and, therefore, deny the same. Defendants are without knowledge or information
6 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint
7 regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants state
8 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
9 prescribing information. Defendants state that the potential effects of Celebrex® were and are
10 adequately described in its FDA-approved prescribing information, which was at all times
11 adequate and comported with applicable standards of care and law. Defendants deny any
12 wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and
13 deny the remaining allegations in this paragraph of the Complaint.

14 190. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 191. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
21 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
22 Complaint.

23 192. Defendants deny any wrongful conduct and deny the remaining allegations in this
24 paragraph of the Complaint.

25 193. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
26 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
27 Complaint.

28 194. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or

1 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
2 Complaint.

3 **Response to Ninth Cause of Action: Loss of Consortium**

4 195. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
5 Complaint as if fully set forth herein.

6 196. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
8 marital status, and, therefore, deny the same. Defendants are without knowledge or information
9 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint
10 regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants deny
11 any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and
12 deny the remaining allegations in this paragraph of the Complaint.

13 197. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 198. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint, including all subparts.

25 199. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
27 marital status, and, therefore, deny the same. Defendants are without knowledge or information
28 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint

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1 regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants state
2 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
3 prescribing information. Defendants state that the potential effects of Celebrex® were and are
4 adequately described in its FDA-approved prescribing information, which was at all times
5 adequate and comported with applicable standards of care and law. Defendants deny any
6 wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and
7 deny the remaining allegations in this paragraph of the Complaint.

8 200. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 201. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
15 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
16 Complaint.

17 202. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 203. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
20 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
21 Complaint.

22 204. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
23 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
24 Complaint.

25 **Response to Tenth Cause of Action: Negligent Infliction of Emotional Distress**

26 205. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
27 Complaint as if fully set forth herein.

28 206. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and
2 Decedent used Celebrex®, and, therefore, deny the same. Defendants are without knowledge
3 or information sufficient to form a belief as to the truth of the allegations in this paragraph of
4 the Complaint regarding Plaintiff's and Decedent's marital status, and, therefore, deny the
5 same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or
6 Decedent injury or damage, and deny the remaining allegations in this paragraph of the
7 Complaint.

8 207. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 208. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint, including all subparts.

20 209. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's
22 marital status, and, therefore, deny the same. Defendants are without knowledge or information
23 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint
24 regarding whether Decedent used Celebrex®, and, therefore, deny the same. Defendants state
25 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
26 prescribing information. Defendants state that the potential effects of Celebrex® were and are
27 adequately described in its FDA-approved prescribing information, which was at all times
28 adequate and comported with applicable standards of care and law. Defendants deny any

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wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

210. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

211. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

212. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

213. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

214. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer For Relief

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in paragraph of the Complaint headed "Prayer for Relief," including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs or Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs or Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs' and Decedent's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs and Decedent was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs' and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiffs' and Decedent's alleged injuries/damages, if any, were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiffs and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by

the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f

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1 to § 6 of the Restatement (Third) of Torts: Products Liability.

2 **Twenty-eighth Defense**

3 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
4 Products Liability.

5 **Twenty-ninth Defense**

6 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead
7 facts sufficient under the law to justify an award of punitive damages.

8 **Thirtieth Defense**

9 30. Defendants affirmatively aver that the imposition of punitive damages in this case
10 would violate Defendants' rights to procedural due process under both the Fourteenth
11 Amendment of the United States Constitution and the Constitution of the State of California,
12 and would additionally violate Defendants' rights to substantive due process under the
13 Fourteenth Amendment of the United States Constitution.

14 **Thirty-first Defense**

15 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and
16 Fourteenth Amendments to the United States Constitution.

17 **Thirty-second Defense**

18 32. The imposition of punitive damages in this case would violate the First Amendment to
19 the United States Constitution.

20 **Thirty-third Defense**

21 33. Plaintiffs' punitive damage claims are preempted by federal law.

22 **Thirty-fourth Defense**

23 34. In the event that reliance was placed upon Defendants' nonconformance to an express
24 representation, this action is barred as there was no reliance upon representations, if any, of
25 Defendants.

26 **Thirty-fifth Defense**

27 35. Plaintiffs failed to provide Defendants with timely notice of any alleged
28 nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks

1 constitutionally sufficient standards for appellate review of punitive damages awards; and (8)
2 otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific*
3 *Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources,*
4 *Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State*
5 *Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

6 **Thirty-ninth Defense**

7 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
8 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
9 instructions with respect to the product's use in the package insert and other literature, and
10 conformed to the generally recognized, reasonably available, and reliable state of the
11 knowledge at the time the product was marketed.

12 **Fortieth Defense**

13 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
14 tested, manufactured and labeled in accordance with the state-of-the-art industry standards
15 existing at the time of the sale.

16 **Forty-first Defense**

17 41. If Plaintiffs or Decedent have sustained injuries or losses as alleged in the Complaint,
18 upon information and belief, such injuries and losses were caused by the actions of persons not
19 having real or apparent authority to take said actions on behalf of Defendants and over whom
20 Defendants had no control and for whom Defendants may not be held accountable.

21 **Forty-second Defense**

22 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
23 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
24 intended, and was distributed with adequate and sufficient warnings.

25 **Forty-third Defense**

26 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,
27 waiver, and/or estoppel.
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Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' and Decedents' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs and Decedent, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs or Decedent.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs and Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Decedent.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs and Decedent were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' and Decedent's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' and Decedent's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

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April 8, 2008

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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